

REMARKS

Claims 1, 2, 14, 16, 27, and 28 have been amended, and new claims 29-60 have been added. Written description support for these amendments is found throughout the original specification. No new matter has been added. Applicant respectfully submits that all pending claims 1-6, 8-10, and 14-60 are in condition for allowance.

Applicant would like to thank the Examiner for participating in a telephone interview on April 26, 2010. During the interview, the subject matter of claim 1 was discussed relative to the conclusions in the office Action (at pp. 14-15) regarding the Calancie reference and the Katims reference. During the interview, it was agreed that Katims does not expressly or inherently disclose “automatically increasing said electrical stimulus in constant increments until said neuro-muscular response is detected.” The Office Action (at p. 14) contended that the Katims reference “inherently” disclosed this claimed feature, but the Applicant explained that Katims is silent on this feature and it was not *necessarily present* (as required by MPEP § 2112) because other manners of increasing Katim’s electrical stimulus (e.g., in non-constant increments) could have been employed. As such, the Examiner agreed that Katims did not expressly or inherently disclose this feature.

Also during the interview, the claim rejections under 35 U.S.C. § 112 and the objections to the specification/claims were discussed. As described below, it was agreed during the interview that these objections and §112 rejections would be withdrawn in light of Applicant’s citation to the teachings in the original specification that provide written description support and enablement.

Claims 27 and 45-60

Claim 27 has been rewritten into independent form with no changes to the previous claim scope. Claim 27 was not subject to any prior art rejections in the Office Action. Claim 27 was instead rejected under 35 U.S.C. § 112, ¶1 for failing to complying with the enablement requirement. As previously described, this rejection was discussed during the April 26, 2010

interview, and it was agreed that this rejection of claim 27 would be withdrawn based upon the enabling teaching set forth in the Applicant's original specification.

Namely, the Office Action contended that the specification did not enable a skilled artisan to perform the claimed method in which an EMG signal has an amplitude value comprising "a peak-to-peak amplitude value greater than the predetermined value." Applicant respectfully disagrees, and submits that the original specification discloses an example of a peak-to-peak amplitude value in terms of a "peak-to-peak height" of the EMG signal. (See Specification at p. 17, lines 4-16; p. 32, lines 6-24; FIG. 6.) Further, Applicant's provisional application also provides an exemplary teaching of a peak-to-peak amplitude value in terms of a "positive hump" and a "negative hump" of the EMG signal. (See Provisional Specification at p. 12, lines 22-23.) In one example, Applicant's FIG. 6 illustrates one example of an EMG signal in response to a stimulus, and the EMG signal includes a peak-to-peak amplitude between the positive peak and the negative peak:

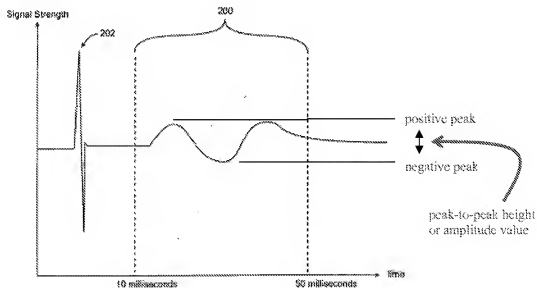


FIG. 6

Accordingly, the original specification provides examples of the "peak-to-peak amplitude" representing the magnitude (or "height" on the graph) between the positive peak and the negative peak of the EMG signal. *As agreed during the April 26, 2010 interview*, these

teachings provide a clear teaching so that a “person skilled in the art can make and use the invention without undue experimentation.” MPEP § 2164.01. Indeed, the MPEP explains that:

As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied.

MPEP § 2164.01(b) (emphasis added). There is no question that the Applicant’s original specification more than satisfies this standard.

It is believed that all rejections against claim 27 have been resolved. Accordingly, the subject matter of claim 21 is patentable over the references cited in the record and is in condition for allowance. Dependent claims 45-60 are patentable for at least the same reasons as claim 27 and for the additional inventive combinations described therein.

Claims 14-17, 26, and 29-44

Claim 14 has been rewritten into independent form with no changes to the previous claim scope. Claim 14 was rejected under 35 U.S.C. § 103 as being unpatentable over Neubardt in view of Calancie and in further view of Katims. Applicant respectfully submits that even if there was an articulated reason that would have prompted a skilled artisan to combine these references as proposed in the Office Action (an issue that is not conceded herein), the proposed combination would nevertheless fail to achieve the method set forth in claim 14.

First, unlike claim 14, none of Neubardt, Calancie, or Katims discloses a method “wherein displaying the onset electrical stimulus current level on the display device includes *visually displaying to said surgeon an electrical current value representing said onset electrical stimulus current level* causing said onset neuro-muscular response for said spinal nerve.” The Office Action (at pp. 14-15) contends that Calancie and Katims “inherently” teaches the use of a monitor that has the ability to display the stimulus intensity. Applicant respectfully disagrees.

The Calancie reference does not disclose any method that includes visually displaying to a surgeon an electrical current value representing an onset electrical stimulus current level. Instead, Calancie explains that only the EMG response waveforms (which are different from an electrical current value) are displayed when printed on “instrumentation tape” for viewing by an

electrophysiologist who subsequently verbalizes with the surgeon. (*See* Calancie at p. 2781 col. 1 (EMG signals are printed on “instrumentation tape”); p. 2782 col. 1 (if an EMG wave was detected by the electrophysiologist, “the electrophysiologist ‘guided’ the surgeon to the exact site of the perforation by continually stating whether EMG was evoked”). Thus, not only does Calancie fail to disclose the claimed display device that shows “an electrical current value representing said onset electrical stimulus current level,” but Calance also fails to disclose any scenario in which the electrical current value on the display device should be “display[ed] to said surgeon.” Clearly, the subject matter set forth in claim 14 is different from the process described in Calancie, and the claimed subject matter cannot be properly characterized as a mere automation of the process described in Calancie.

The Katims reference is also lacking. Namely, the Katims reference does not teach that a display device showing “an electrical current value representing said onset electrical stimulus current level” should be “display[ed] to said surgeon.” Instead, Katims discloses that a “constant alternating current stimulus” is applied to a patient by “manually controlling” the current intensity knob 20. (*See* Katims at col. 14, line 67 to col. 15, line 2; FIG. 2.) Nothing indicates that the knob somehow displays an electrical current value, especially because the intensity buttons 21/22 can also be used to adjust Katims’ constant alternating current stimulus without moving the knob 20. In addition, nothing in the Katims reference indicates that an electrical current value should be displayed to a surgeon operating on the patient.

Accordingly, both Calancie and Katims fail to disclose the same features recited in claim 14. Indeed, even if Katims’ device 9 (FIG. 2) was implemented in Calancie’s spinal surgery process, nothing in these two references indicates that an electrical current value (representing said onset electrical stimulus current level) should be displayed to the surgeon.

For any of these reasons, the proposed combination of Neubardt, Calancie, and Katims would nevertheless fail to achieve the method set forth in claim 14 even if there was an articulated reason that would have prompted a skilled artisan to combine these three references as proposed in the Office Action (an issue that is not conceded herein). Applicant respectfully submits that claim 14 is patentable over the prior art of record. Dependent claims 15-17, 26, and

29-44 are patentable for at least the same reasons as claim 14 and for the additional inventive combination recited therein.

Claims 1-6, 8-10, 18-26, and 28

Independent claim 1 and particular dependent claims were rejected under 35 U.S.C. § 103 as being unpatentable over Neubardt in view of Calancie and in further view of Katims. Applicant respectfully submits that even if there was an articulated reason that would have prompted a skilled artisan to combine these references as proposed in the Office Action (an issue that is not conceded herein), the proposed combination would nevertheless fail to achieve the method set forth in amended claim 1.

First, unlike claim 1, none of Neubardt, Calancie, or Katims discloses the operation of “detecting an onset neuro-muscular response having an amplitude greater than a predetermined positive value in response to the application of said electrical stimulus to said first aspect of said bone by *automatically increasing said electrical stimulus in constant increments until said onset neuro-muscular response is detected* by one or more of the EMG sensor electrodes.” Indeed, the Office Action does not contend that Neubardt or Calancie provides such a teaching. Instead, the Office Action relies upon the Katims reference for a purported disclosure of automatically increasing said electrical stimulus “in constant increments” until said onset neuro-muscular response is detected. (See Office Action at p. 14.) In particular, the Office Action contends that Katims teaching in col. 7 and col. 34 “inherently” discloses this feature:

As stated in the above rejection, Katims teaches the “constant increments” of an electrical stimulus, in Column 7, lines 19-32; and Column 34, lines 9-23. The automatic determination of a threshold response to an applied electrical stimulus inherently requires a constantly incrementing the stimulus level until a response is elicited.

See Office Action at p. 14. This contention is not correct. The cited portion of the Katims reference is utterly silent on how the electrical stimulus is increased (constant or non-constant increments):

The present invention includes an automated apparatus for CPT determination, diagnostics and therapeutics. This apparatus is able to conduct CPT determinations independent of physician or technician for the evaluation of input data (i.e., patients response and electrical stimulus parameters). This test is capable of being conducted by the patient. The apparatus incorporates a means by which thresholds are automatically determined, while at the same time monitoring the responses of the subject being tested to determine consistency of subject responses, which provide an index of the reliability of the measurement being obtained, and at the same time aids in the detection of possible deception or malingering by the patient being tested.

20

25

30

← a disclosure of
"constant
increments" is
not necessarily
present

See Katims at col. 7, lines 19-32. *As agreed during the April 23, 2010 interview*, Katims does disclose not a method in which it is "necessarily present" (the standard under MPEP § 2112 for inherency) to automatically increase the electrical stimulus in constant increments. Indeed, Katim's electrical stimulus may be adjusted "using random steps." See Katims at col. 26, line 48.

As such, the Office Action improperly concluded that the Katims reference inherently discloses the claimed feature of automatically increasing said electrical stimulus in constant increments until said onset neuro-muscular response is detected. For this reason alone, the proposed combination of Neubardt, Calancie, and Katims would nevertheless fail to achieve all elements of the method set forth in claim 1. Applicant respectfully requests withdrawal of the §103 rejection of claim 1.

Second, unlike claim 1, none of Neubardt, Calancie, or Katims discloses the operation of "detecting an onset neuro-muscular response *having an amplitude greater than a predetermined positive value* in response to the application of said electrical stimulus." The Office Action contends that the Calancie reference "inherently" discloses this claimed feature:

Calancie et al inherently discloses the claim limitation: EMG

electrodes "outputting an EMG signal having an amplitude greater than a predetermined value". Based on the current claim language, the "predetermined value" can be interpreted as zero. Since Calancie et al acquires an evoked EMG response, the EMG response inherently has an amplitude greater than zero.

See Office Action at p. 14. This contention is not correct. Calancie teaches that the system merely notifies whether *any* EMG signal exists, not whether there is an EMG signal having a amplitude greater than a predetermined positive value. (See Calancie at p. 2782 col. 1 (if any EMG wave is viewed by the electrophysiologist, “the electrophysiologist ‘guided’ the surgeon to the exact site of the perforation by continually stating whether EMG was evoked”). Nothing in Calancie suggests that the particular amplitude of the EMG signal is relevant to the process of detecting an onset neuro-muscular response. According to Calancie’s teaching, the only thing that matters is if any EMG signal is printed onto the instrumentation tape that records the EMG signal. Here again, the process disclosed in Calancie is different from that recited in claim 1, and the claimed subject matter cannot be properly characterized as a mere automation of the process described in Calancie.

For this second reason alone, the proposed combination of Neubardt, Calancie, and Katims would nevertheless fail to achieve all elements of the method set forth in claim 1. Applicant respectfully requests withdrawal of the §103 rejection of claim 1.

Third, unlike claim 1, none of Neubardt, Calancie, or Katims discloses the operation of *“displaying on an integrated display device of said neurophysiology system while viewed by a surgeon operating on the patient’s spine an onset electrical stimulus current level* which causes said onset neuro-muscular response.” The Office Action (at pp. 14-15) contends that Calancie and Katims “inherently” teaches the use of a monitor that has the ability to display the stimulus intensity. Applicant respectfully disagrees.

The Calancie reference does not disclose any method that includes displaying a stimulus current level on an integrated display, and certainly does not disclose that such a stimulus current level should be displayed that is viewed by a surgeon. Instead, Calancie teaches that only the EMG response waveforms (which are different from an electrical current value) are displayed when printed on “instrumentation tape” for viewing by an electrophysioogist who subsequently verbalizes with the surgeon. (See Calancie at p. 2781 col. 1 (EMG signals are printed on “instrumentation tape”); p. 2782 col. 1 (if an EMG wave was detected by the electrophysiologist, “the electrophysiologist ‘guided’ the surgeon to the exact site of the perforation by continually stating whether EMG was evoked”). Thus, not only does Calancie fail to disclose the claimed

integrated display device of the neurophysiology system that shows “an onset electrical stimulus current level which causes said onset neuro-muscular response,” but Calancie also fails to disclose any scenario in which the onset electrical stimulus current level on the integrated display device should be “viewed by a surgeon operating on the patient’s spine.” Yet again, the subject matter set forth in claim 1 is different from the process described in Calancie, and the claimed subject matter cannot be properly characterized as a mere automation of the process described in Calancie.

The Katims reference is also lacking this feature of the claimed method. In particular, the Katims reference does not teach that an integrated display device showing “onset electrical stimulus current level” should be displayed “while viewed by a surgeon operating on the patient’s spine.” As previously described, Katims discloses that a “constant alternating current stimulus” is applied to a patient by “manually controlling” the current intensity knob 20. (*See* Katims at col. 14, line 67 to col. 15, line 2; FIG. 2.) Katims does not teach that the knob 20 somehow displays an onset electrical stimulus current level, especially because the intensity buttons 21/22 can also be used to adjust Katims’ constant alternating current stimulus without moving the knob 20. In addition, nothing in the Katims reference indicates that an onset electrical stimulus current level should be displayed while viewed by a surgeon operating on the patient’s spine.

Thus, both Calancie and Katims fail to disclose the displaying operation recited in claim 1. Indeed, even if Katims’ device 9 (FIG. 2) was implemented in Calancie’s spinal surgery process, nothing in these two references indicates that electrical stimulus current level (which causes said onset neuro-muscular response) should be displayed while viewed by a surgeon operating on the patient’s spine.

For any of the aforementioned reasons, the proposed combination of Neubardt, Calancie, and Katims would necessarily fail to achieve all elements of the method set forth in claim 1 even if there was an articulated reason that would have prompted a skilled artisan to combine these three references as proposed in the Office Action (an issue that is not conceded herein). Applicant respectfully submits that claim 1 is patentable over the prior art of record. Dependent

claims 2-6, 8-10, 18-26, and 28 are patentable for at least the same reasons as claim 1 and for the additional inventive combination recited therein.

Compliance with 35 U.S.C. § 112

As previously described, the Office Action rejected a number of claims under 35 U.S.C. § 112, ¶1 or ¶2. During the April 23, 2010 interview, it was agreed that these § 112 rejections would be withdrawn along with the objections to the specification and claims.

Regarding the §112, ¶1 rejection of claim 5, the Applicant noted during the April 23, 2010 interview that the claim limitation is fully supported by the specification. Namely, the original specification at FIGS. 2-3, page 18, lines 10-22 and page 25, lines 6-12 provides an ample teaching of a system that can increase the electrical stimulus by constant current increments from within the range of 0.5 to 4 milliamps.

Regarding the §112, ¶1 rejection of claim 16, the Applicant noted during the April 23, 2010 interview that a grammatical error in the claim language would be corrected. The amendment to claim 16 is made herein.

Regarding the §112, ¶1 rejections of claim 28, it was agreed during the April 23, 2010 interview that the claim would be fully is fully supported by the specification if the term “about” was removed. In particular, the original specification at page 15, lines 5-14 and page 18, lines 10-22 provides a sufficient teaching of a predetermined positive value selected from a range of about 60mV to about 80mV. Further, it was agreed during the April 23, 2010 interview that these cited portions and other portions of the specification enable a person of ordinary skill in the art to understand how to perform the claimed method (the step of detecting the onset neuro-muscular response).

Request for Reconsideration

Applicant submits that claims 1-6, 8-10, and 14-60 are patentable over the prior art of record. Reconsideration and allowance is respectfully requested.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the claim amendments herein do not signify concession of unpatentability of claims 1, 2, 14, 16, 27, and 28 prior to the amendments herein. Applicant hereby specifically reserves the right to prosecute the previously presented subject matter of claims 1, 2, 14, 16, 27, and 28 (prior to the amendment herein) in a continuation application. Applicant hereby specifically reserves the right to prosecute claims of different or broader scope in a continuation application. The Patent Office should infer no (i) adoption of a position with respect to patentability, (ii) change in the Applicant's position with respect to any claim or subject matter of the invention, or (iii) acquiescence in any way to any position taken by the Office Action, based on amendments made herein.

Please apply \$1,404 in payment of the excess claims fee to deposit account 06-1050. If necessary, please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: June 1, 2010

/Michael T. Hawkins/
Michael T. Hawkins
Reg. No. 57,867

Fish & Richardson P.C.
Telephone: (612) 335-5070
Facsimile: (877) 769-7945